IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S COUNTER DEPOSITION DESIGNATIONS OF DENNIS MILLER, MD, TAKEN NOVEMBER 15, 2013 and MAY 13, 2014

BSC Counter Designation	Objection	Plaintiffs Counter Designation to BSC Counter Designation
dm111513, (Page 182:8 to 182:19) **182** **8 Q All right. It is your position as you sit here today** **9 that polypropylene mesh is still appropriate for** **10 permanent implant in the female pelvic floor?** **11 A Polypropylene has been used for more than 30 years** **12 and we have seen good clinical results. I have my** **13 own outcomes, my own experience, those of my mentors,** **14 hernia surgeons for their use in the abdominal** **15 hernias, and we've seen its use in the pelvic floor**	**182:8-182:19 FRE 403, Cumulative, Nonresponsive**	

16 for many, many years and myself, as do many other 17 urogynecologists, we do still feel, we continue to 18 perform those procedures as we always have because of 19 the benefits that we can afford our patients.		
dm111513, (Pages 183:5 to 184:2) 183 5 Q I'm not asking you about anybody other than yourself. 6 As the person who brought the concept that became 7 Pinnacle to Boston Scientific, you as you sit here 8 remain of the belief that polypropylene mesh is 9 appropriate for permanent implant in the female 10 pelvis? 11 A Sure. Because it seems as if you don't want me to be 12 talking about the fact that there is broad use among 13 board certified urogynecologists for -- in other 14 words, that there is less controversy among my 15 colleagues and that's the basis upon which I am 16 making that decision. Therefore, it's the basis upon 17 which I'm answering your question. 18 Q We can ask it again. I'm asking you, Doctor, as the 19 person who brought the concept that became Pinnacle 20 to Boston Scientific, you remain of the belief that 21 polypropylene mesh is appropriate to be permanently 22 implanted in the female pelvis? 23 A With long experience to back that up, yes. 24 Q And the interesting thing about the long experience 184 1 that you have repeatedly gone to is to cite 2 experience from hernia mesh?	**183:5-183:17 FRE 403, Cumulative 183:24-2 FRE 403, Cumulative**	
dm111513, (Page 184:4 to 184:7)	**184:4-184:7**	

184 4 A No. When I say long experience, I'm referring to my 5 own personal experience and the experience of the 6 large numbers of surgeons in my field. When I said 7 long experience, that was what I was referring to.	FRE 403 Cumulative	
dm111513, (Page 184:20 to 184:24) 184 20 Q That's where I'm getting at, Doctor. As you sit 21 here, you don't know of an expert, don't have a 22 consultation, don't have an investigation as to the 23 breakdown over time of polypropylene mesh in the 24 female pelvis?	184:20-187:2 FRE 401, 402 403, 701, 702	
dm111513, (Pages 186:7 to 187:2) 186 7 A I attend lectures by material scientists and by 8 experts in the field, and one of our most trusted 9 members is Pam Moalli of the University of 10 Pittsburgh, and my understanding is that either the 11 degradation is a misunderstanding of what's happening 12 on the surface of the polypropylene or one thing that 13 I can know for myself clinically is that the 14 degradation is not clinically relevant because I've 15 had long experience, and that's where I think hernia 16 surgeons would then come in is unless you'd propose 17 that it only degrades in the pelvis and somehow does 18 not degrade elsewhere, but that's been -- all of 19 those things add up. 20 All of this experience, 30 years of experience 21 and our own experience, when I'm talking about in the	184:20-187:2 FRE 401, 402 403, 701, 701 Nonresponsive	

22 pelvic floor because in the University of Wisconsin, 23 they were doing it in the 1980s, has taught all of us 24 surgeons, myself included, so I am answering for 187 1 myself, that polypropylene degradation is not a 2 clinically relevant problem.		
dm052314, (Page 349:1 to 349:13) 349 1 Q MUS. That's a question of -- COI is conflicts of 2 interest, correct? 3 A Correct. 4 Q When you were asked to join, did you have to reveal 5 any conflicts of interest or potential conflicts of 6 interest? 7 A Yes. We actually had to go through it because the 8 initial view of some was that my -- since my 9 royalties are specific to Pinnacle and Uphold, that I 10 wouldn't. And I just felt that it was best to 11 disclose broadly. And so, yes, I provided the 12 disclosure that I receive royalties on a -- not on 13 slings but on a prolapse mesh. So yes.	349:1-13 FRE 403	
dm052314, (Page 368:3 to 368:11) 368 3 What were you talking about? 4 A There was a local doctor by the name of Christopher 5 Walsh who was getting pushback -- he was getting 6 pushback from his hospital on the use of slings 7 because there was just all of this vague information. 8 And he already took this to his employer and said, 9 "Look, slings are the standard of care." 10 That's what I'm remembering. I 11 think -- I think there were others, though.	388:3-11 FRE 403, 802	

dm052314, (Page 381:6 to 381:10) **381** **6 Q Here's a statement that I've heard you say several** **7 times, so let's flesh it out. "Used by 99 percent of** **8 AUGS members."** **9 MR. ANIELAK: Do you see it on the --** **10 THE WITNESS: I do see that on the page.**	**381:6-10** **FRE 401, 402, 403**	
dm052314, (Page 382:1 to 382:12) **382** **1 Q And that statement that you keep using comes from a** **2 survey of AUGS members?** **3 A The statement actually comes from being a member** **4 of the society and being aware of the practices** **5 in Milwaukee and Wisconsin, throughout the** **6 country.** **7 It's so common knowledge. The survey** **8 allows us to state that obvious fact. And if someone** **9 wants to just randomly challenge it, we've at least** **10 got some support to what is just common knowledge.** **11 It is the standard of care throughout** **12 the world.**	**382:1-12** **FRE 401, 402, 403, 701, 702**	***dm052314, (Page 382:13 to 382:15)*** ***382*** ***13 Q And what you're talking about is the use of sling*** ***14 mesh?*** ***15 A Right. That's what this is about.*** **dm052314, (Pages 383:9 to 384:7)** ***383*** ***9 When you did your edits on the position*** ***10 statement, you did not have a reference for the*** ***11 statement: "99 percent of AUGS" members use MUS --*** ***12 midurethral -- slings.*** ***13 A That was a comment, not an edit. And yeah, I did not*** ***14 have the specific reference for both of those*** ***15 statements, that over 3 million slings have been used*** ***16 worldwide. You know, they're obvious statements*** ***17 that we all know, but the reference I didn't have at*** ***18 my fingertips.*** ***19 Q Right. It says, "Over 3 million MUS" -- that's*** ***20 midurethral slings -- "have been placed worldwide,"*** ***21 right?*** ***22 A Yes.***

		23 Q "And these procedures are used by greater than *24 99 percent of AUGS members."* *384* *1 And you say, "I don't have a reference* *2 for this. Charlie, can you add it?"* *3 A Right.* *4 Q Now, the over 3 million MUS placed worldwide --* *5 A Um-hmm.* *6 Q -- how is that derived?* *7 A I don't know.*
dm052314, (Pages 458:9 to 461:16) **458** **9 Q Dr. Miller, please introduce yourself to the jury.** **10 Tell the jury a little bit about yourself.** **11 A My name is Dennis Miller. I'm a urogynecologist in** **12 Milwaukee, Wisconsin.** **13 Q And tell the jury a little bit about your personal --** **14 personal life. Are you married? Do you have kids?** **15 Tell me a little bit about your -- your personal** **16 life.** **17 A I am married. I have three daughters, and I live in** **18 a suburb of Milwaukee called Whitefish Bay.** **19 Q And how did you -- what was your drive to become a** **20 physician? How did you ultimately decide to enter** **21 that field?** **22 A Well, it was the nobility of it. I've always wanted** **23 to be a physician. In fact, there's a picture of me** **24 at four years old -- we didn't have any doctors in** **459** **1 our family. We had all salesmen in our family.**	**Boston Scientific has previously designated this testimony and Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

And they always wanted a doctor, so my mother put me into Dr. Kildare shirts at four years old. And I think I've known ever since then that that's what I would be. **Q We're going to talk a little bit about your educational background and your medical practice, but before we do that, orient the jury about your role with Boston Scientific and its medical devices in terms of the Pinnacle device.** **A Yes. I've been a urogynecologist for 25 years or so, and I learned prolapse repair from Lester Ballard at the Cleveland Clinic and learned mesh repairs from Dr. Tom Julian at the University of Wisconsin in the 1980s.** **So over this long experience, I've been able to see clearly some ideas, and one of the ideas that I've had was for a fixation device for how to get mesh into the deepest part of the vagina.** **So I brought that idea to Boston Scientific, and they decided that they would create this fixation device. And I subsequently, then, worked with a series of physicians and engineers at iterating that device that eventually became known as** **460** **Pinnacle and Uphold, which are fixation devices that are in this category that we're talking about.** **Q Okay. And we're going to talk in detail about your involvement with Boston Scientific in that process, but before we do that, tell the jury a little bit**		

about your educational background, where did you go to school, when did you graduate, that sort of thing. A I went to the Medical College of Wisconsin and -- for medical school and did residency at the Medical College of Wisconsin affiliated hospitals. I did a fellowship in urogynecology in -- technically at that time it was called Advanced Pelvic Surgery in 1988 and 1989 before moving back to Milwaukee to become the first urogynecologist in the area. Q And then since completing that fellowship in '88 and '89 and moving back to Milwaukee, have you been in private practice? A I've been in private practice since 1989 with a large multidisciplinary group. Q And has the nature of your practice been about the same since 1988 -- '88 and '89? A Yes. I have restricted my practice to the treatment of pelvic floor disorders, which are essentially 461 incontinence of urine and prolapse of the pelvic organs. And I take referrals from doctors throughout Wisconsin for that. Q Tell the jury what pelvic organ prolapse is. A Pelvic organ prolapse is a loss of support of the vagina and the organs that are attached to it. It results in essentially the vagina trying to turn inside out. If you think of it like the finger of a glove, prolapse is where the vagina		

10 and the organs that are associated with it begin to 11 just essentially turn inside out. 12 And it causes this really significant 13 distress when sitting, when standing, when trying to 14 walk. It makes sex very difficult, and it's a source 15 of great embarrassment. Can be associated with a lot 16 of urinary and bowel complaints as well.		
dm052314, (Pages 462:3 to 464:22) 462 3 Q Have you been involved with training other 4 urogynecologists in the area in these -- in treating 5 these disorders? 6 A Yes. Well, you know, I was the first urogynecologist 7 in the area. And I was responsible for many years 8 for teaching both residents and private practice 9 physicians the standards of care in -- for these 10 disorders. 11 Q In terms of professional societies, are there 12 professional societies of urogynecologists? 13 A Yes. The main society of urogynecologists is called 14 the American Urogynecologic Society, AUGS. But we 15 also have our International Urogynecologic 16 Association, or IUGA, and the International 17 Continence Society. 18 And then on the urology side we have 19 the Society for Urodynamics and Female Urology. 20 Q And do you belong to those societies? 21 A I don't belong to the urology society at this time, 22 but I do belong to the gynecologic society. 23 Q And what is the role of those societies? What do 24 they do?	Boston Scientific has previously designated this testimony and Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

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A They provide education for both general OB/GYNs and for urogynecologists. And they provide a -- both a virtual and a real meeting place for specialists in the treatment of incontinence and prolapse so that we can get together both, you know, online, in writing, with video conferencing, as well as in our meetings.

And so we -- we're involved in -- in setting the standards of care for the treatment of these disorders.

Q And have you had leadership positions in those -- in those societies?

A I've not had leadership positions in those societies, but I have been selected by the leadership to participate in committees. Like I just got off of a three-year stint with the scientific program committee.

Q Okay. Any other committees that you've been a part of selected by the leadership of those organizations?

A Well, I was -- I was selected to be the chair of the inaugural year of the mesh special interest group.

Q And tell the jury, what is that? What was the mesh special interest group of the AUGS society?

A Well, special interest groups in general are

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becoming increasingly popular in all societies. It's a more informal group where physicians can get together and discuss current therapies and exchange

4 ideas and is a good resource for educational venues 5 as well. 6 Q Okay. Have you published in the area of transvaginal 7 mesh and stress urinary incontinence? 8 A Because of my role and private practice nature, I've 9 had limited publications. But I've published on the 10 office management of stress urinary incontinence, 11 I've published a five-year outcome study of prolapse 12 repairs, and I recently published a paper on informed 13 consent for -- proper informed consent for vaginal 14 mesh. 15 (Exhibit 1037 marked for identification.) 16 BY MR. PIRTLE: 17 Q Dr. Miller, I've marked as Deposition Exhibit 18 No. 1037 a presentation that's titled "Overview of 19 Boston Scientific's Pelvic Floor Products and 20 Risk-Benefit Assessment" in April of 2011. 21 Do you see that? 22 A I do.		
dm052314, (Pages 465:17 to 477:2) 465 17 What are the surgical treatment 18 options that -- for pelvic organ prolapse? 19 A Well, this is a very important aspect to all of our 20 discussion because we treat prolapse in a variety of 21 ways. For myself, I use all three of these methods 22 to treat prolapse, and it's all about patient 23 selection and who the patient is and who you are as a 24 surgeon. 466 1 And so the first approach is the 2 so-called native tissue repair, which is the anterior	Boston Scientific has previously designated this testimony and Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

and posterior repair, which is lifting of the vaginal tissues. It's been around since about 1917, with suspension of the vagina. And generally, if the woman has a uterus, it involves performing a hysterectomy as well. Q And are there limitations to that type of surgery in terms of drawbacks? A Yeah. Every textbook in OB/GYN dating back even into the '50s has referred to the unfortunate degree of failure. You know, when you talk to women who are older, they'll tell you that their physicians told them that the repairs would only last five years. And they'll be familiar, "Oh, yes, my mother had that done two, three, four times." And so one of the main limitations of the native tissue repair that mean we can't use it in every single patient is that there's substantial failure. And the other aspect to it is, you know, there's a lot of suture entrapment issues, and there's binding that happens. In some studies the painful intercourse rates are 50 percent of the 467 patients. And so there's -- there is limitations to any surgery, of course. And I performed native tissue repair in a substantial portion of my patients, but those are the limitations to it. Q And then the second bullet point is abdominal		

colposacropexy. Tell the jury what that is. A It's important to suspend the vagina at its deepest part. That's -- that's really the -- the center tent pole of your tent. And the colposacropexy is an attempt to fixate the vagina inside the abdomen going from above. The problem is the vagina won't reach the fixation point, so you generally have to add -- as a part of this operation, you always have to add a graft material of some type. Polypropylene is currently considered the best, and so it is the most common graft used. So polypropylene mesh is generally used to suspend the vagina. But, again, you have to move the colon, you have to move the rectum and the bladder, and you have to expose the sacrum in order to fixate this piece of mesh from the vagina to the sacrum. Q So how does abdominal -- abdominal sacrocolpopexy 468 differ from transvaginal mesh in bullet point 3? What's the difference between those two? A The difference is the approach. Mesh is placed generally laparoscopically or robotically from above after the performance of a hysterectomy, versus the transvaginal mesh is taking that same polypropylene mesh and inserting it transvaginally. Q And are there other limitations or drawbacks that you have to consider before performing an abdominal sacrocolpopexy?		

12 A Well, it's a good surgery as well, as is native **13 tissue repair. That's why I perform all three.** **14 But the limitations are, for one** **15 thing, the complexity of the operation; the very act** **16 of having to move the colon and the rectum and the** **17 bladder. And there's a 1 percent incidence of bowel** **18 obstruction because the mesh is inside of the** **19 abdomen.** **20 Q And then the third bullet that you identify on the** **21 surgical options says "Transvaginal" -- "Transvaginal** **22 (vaginal mesh)."** **23 Tell the jury what that means.** **24 A Well, that means taking that same polypropylene mesh** **469** **1 or -- you know, in -- other grafts can be used,** **2 biological grafts can be used, but taking a graft,** **3 generally polypropylene, and fixing it from a** **4 transvaginal approach.** **5 So you don't need to move those other** **6 organs in order to get to the place where you want to** **7 fixate -- where you want to fixate the mesh. So it's** **8 another one of the options for doing it.** **9 Q And both the abdominal sacrocolpopexy and the** **10 transvaginal mesh involve using a graft or a mesh** **11 material of some kind?** **12 A Yes.** **13 Q And what's the purpose of that? What function does** **14 the mesh itself provide? Why is it used in those** **15 surgeries?** **16 A Well, the goal -- the goal of it is to attempt to**		

increase the durability of that repair because, you know, what we've -- what we've known for many years, and I've seen in my own practice even, is that you -- you can't expect all these repairs to -- to last over time. And the -- the introduction of mesh is about improving the durability of the repair. Q Has -- transvaginal mesh, has it gone through 470 developments over time? A Yes. Transvaginal mesh has been around, as I said, since the 1980s. And I first saw it when performed by Dr. Tom Julian in Madison, who was one of the early proponents and one of the early investigators to publish on it. And for many years we would cut our mesh and fixate it with suture or with the Capio device. There are a variety of ways of putting them -- putting the mesh in place. But one of the challenges in doing it -- and this is where the devices came in -- is you're trying to perform surgery through what is essentially a very small opening. The vaginal opening -- to enter through the vaginal opening is difficult, particularly because the most important part of the repair is something that's 5 or 6 inches away deep inside. And so that's where the evolution came in, how can we have a more effective fixation? How		

21 can we do a better job of providing a way to deliver 22 the mesh into the play -- into where we want it to 23 be? 24 Q I want to flesh this out a little bit more. 471 1 If you could turn over to slide 19 and 2 explain to the jury what this demonstrates in terms 3 of the evolution of vaginal mesh. 4 A When you look at the top left, the mesh sheets, 5 that's -- that's how mesh came. And so mesh was then 6 introduced in a variety of ways. 7 And by 2000, surgeons began to -- 8 beginning in Australia and Italy and France and the 9 U.S., particularly Tom Julian, began to customize 10 those shapes. 11 But if you look at them, they were all 12 sort of irregular, and there was a lack of 13 reproducibility. And so there was this very 14 inconsistent way of fixing the mesh into place and 15 inconsistent shapes to the mesh going through what is 16 this difficult opening. 17 And then on the bottom -- 18 Q So before we go to the bottom, so on the top when 19 we -- these sheets of mesh, the square sheets, and 20 then in the middle of the page the one that's cut to 21 shape, are these polypropylene sheets of mesh? 22 A Yes. The ones you see here are polypropylene. 23 Q And so was polypropylene mesh being used to treat 24 pelvic organ prolapse back in -- back this far? 472		

A You know, my practice goes back to 1989, and so it's hard for me to comment about prior to 1989. But yes, certainly throughout my entire career I've been aware of surgeons using grafts, and particularly polypropylene, to reinforce their repairs. **Q And then take the jury, then, from the first two -- the top, the three pictures on the top, to the bottom.** **What's the advancement that was made, then, after 2004 when we start talking about first-generation kits?** **A Well, surgeons in general started to talk together about ways of improving the ability to fixate the mesh, to deliver it.** **And we started talking about, you know, we know where we want it to go and we know what we want to do; we want to fix it. But just how do you do it? We need a new hammer; we need a new screwdriver.** **And industry became involved with their engineers at creating fixation devices. And the first generation was to use -- can I grab this?** **Q Sure.** **A -- to use these trocars and to pass them through the** **473** **skin and through the buttock area and just lateral to the vagina and have it enter the vagina at its topmost place. And that really improved substantially our ability to get mesh into place.** **But, you know, we're -- we're always**		

trying to move forward. And one of my thoughts was, Can we do this without passing these trocars? And so could we fixate the mesh by going in through the same incision and yet still reach that area 5 or 6 inches away? Q So the -- what is the device that you're holding in your hand? A This is a needle that is from a Prolift device. Q Okay. And that was part of a device that came on the market prior to the Pinnacle and Uphold devices? A That is correct. (Exhibit 1038 marked for identification.) BY MR. ANIELAK: Q I've marked as Deposition Exhibit No. 1038 a presentation that has your name on the outside of it. Do you see that? A Yes. Q And this was a presentation that you made in 2007? A Yes. 474 Q And I want to talk about a couple of your slides in here to flesh out this discussion regarding the medical devices that were on the market prior to the Pinnacle device, okay? If you turn over to slide 4, which is 658. So in terms of the history of the development of medical devices that treat pelvic organ prolapse, tell the jury what these devices are. A Apogee/Perigee was the first device to market; Prolift second; and Avaulta third, which are fixation		

devices to improve the way that we get the mesh to the desired fixation spots and to secure it down. And so they're just examples of using those needles. All relatively similar needle techniques to introduce the mesh. Q And did these devices use polypropylene mesh? A Yes. Q If you turn over to the next slide. And what -- what are you conveying here when you're talking about the current lift kit advantages? And before you get into more detail, you're talking about the devices that were on the market prior to Pinnacle; is that right? 475 A Apogee/Perigee, Prolift, and Avaulta. Q And what were some of their advantages? A Well, for years, surgeons had been introducing mesh with no real reproducibility and with a variety of different fixation devices. The so-called lift kits provided a way to reproducibly get the mesh into place, and it provided an amount of adjustability because of the wings that you don't have when you just sew it into place; you're locked into the location where you sew it in. And it avoids sutures which encircle the tissues and can compress the tissues and cause ischemia. And the suture -- the suture fixation of the sacrospinous ligament is associated with		

16 6 percent incidence of buttock pain. And so it 17 allows you to avoid those sutures and allows you to 18 easily get to the location you wanted to get to. 19 Q When you turn to the next page, you discuss some of 20 the limitations of the devices that were on the 21 market prior to Pinnacle; is that right? 22 A Yes. 23 Q And what were some of those limitations of the 24 medical devices that were on the market to treat 476 1 prolapse prior to Pinnacle? 2 A Well, they were good -- they were good devices, and 3 they were being used safely. I had good experience 4 with them. But it did strike me that you're passing 5 these needles through anatomy that you can't see and 6 in proximity to neurovascular structures. And so I 7 saw the advantage of being able to introduce the mesh 8 directly through the vaginal incision. 9 Q So tell the jury why passing the needles through 10 unfamiliar anatomy, why is that a bad thing? 11 A Well, it's not a bad thing. 12 Q Okay. Tell the jury what the limitation is of that 13 technique. 14 A In medicine, less is more, and you always want to 15 move forward to increasing simplicity. And passing 16 these needles adds another step going through 17 tissues that have nerves and blood vessels in them. 18 And while -- while that's a path that we are 19 generally good at doing, if I can do it directly		

20 through the incision, I'm going to -- I'm going to 21 want to do that. 22 Q Okay. What's the advantage of doing it directly 23 through the incision as the Pinnacle device does? 24 A I'm not passing through those structures. I'm 477 1 bypassing them. I can directly visualize the 2 structure I want to fixate to.		
dm052314, (Pages 477:20 to 478:23) 477 20 Q And did you come up with an idea to avoid some of 21 these limitations that you identified with the 22 current devices that were on the market? 23 A You know, what I did is combine existing 24 technologies. The Capio device has been used for 478 1 years to fixate mesh into place. 2 And I provided a way to fixate the 3 mesh through the sacrospinous ligament at that true 4 level 1 support by simply introducing the instrument 5 under direct visualization directly to the ligament 6 and then being able to use only a short wing of 7 support and no sutures. 8 Q Okay. And did -- explain to the jury physically how 9 you were able to avoid the trocars. 10 And maybe you can demonstrate with the 11 devices that are there. How did you ultimately avoid 12 using the trocars? 13 A So one of the difficulties in performing this 14 surgery -- and this gets technical, but -- is you 15 have to pass it up and then retrieve it back, again,	Boston Scientific has previously designated this testimony and Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

16 through this narrow tube at a distance away from you. **17 So if you're coming from the outside** **18 in, you've got a wide arc to get up, and that** **19 requires a wide arc to get back.** **20 What this utilized is this existing** **21 technology to simply go to the space and pass it, and** **22 then you can bring that mesh back from the fixation** **23 point directly because of the size and the shape.**		
dm052314, (Pages 480:5 to 482:20) **480** **5 Q So the Polyform mesh that ultimately became the mesh** **6 that was in Pinnacle, was that already being marketed** **7 at the time that Pinnacle came on the market?** **8 A Polyform was being used by surgeons throughout the** **9 world.** **10 Q And that particular mesh for the Pinnacle device was** **11 made of polypropylene?** **12 A Correct.** **13 Q And had polypropylene been used for many years by** **14 your gynecologic surgeons to repair pelvic organ** **15 prolapse?** **16 A That is correct.** **17 Q And that was the slide that we looked at earlier** **18 that indicated that polypropylene mesh had been used** **19 since at least the 1980s?** **20 A Correct.** **21 Q So you came up with this idea to use the Capio device** **22 and to deliver polypropylene mesh and avoid the** **23 trocars.** **24 Tell the jury essentially, then, the** **481** **1 process. When you had the idea, what happened? How**	**Boston Scientific has previously designated this testimony and Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

did you ultimately get hooked up with Boston Scientific? **A Well, after this concept was realized in my mind, I presented the concept to Boston Scientific, that they could make a device that would do this. They could create a fixation device that would take their mesh and introduce it in a better way.** **So I presented that idea to them in August of 2005. And after that time, I agreed to work with a series of doctors and engineers at iterating what eventually became as a device, the Pinnacle and Uphold device.** **Q And how did you work with those engineers and physicians to essentially develop what became the Pinnacle device?** **A Well, I described and drew my concept for mesh fixation to them, and then the engineers would go to a prototyping company and iterate it and create essentially a prototype of it.** **We then had a series -- a whole series of many labs where we would implant it into cadavers and see the advantages and disadvantages of that iteration.** **482** **And then the engineers would go back and reprototype it. And then eventually, based on what other surgeons were saying that they wanted and how they saw this best, and then it would get reiterated again until it became in its final design**		

6 freeze. 7 Q So approximately how long did that take from the time 8 that you went to Boston Scientific until Pinnacle 9 ultimately reached the market? 10 A Well, the first Pinnacle was performed January 2008, 11 so that's two and a half years for that. 12 Q And then as part of your bringing the idea to Boston 13 Scientific, did you essentially negotiate a contract 14 with Boston Scientific for your idea? 15 A I did. I negotiated to have a royalty because this 16 became a device that they were then going to be able 17 to sell, and so... 18 Q And did you ultimately receive royalties for the 19 Pinnacle device? 20 A I did.		
dm052314, (Pages 491:16 to 492:9) 491 16 Q And in terms of your overall experience with 17 the Pinnacle device in terms of it successfully 18 treating pelvic organ prolapse, what has been 19 your experience? 20 A You know, I've now had five years of experience with 21 the device. And I see all of my patients back, and 22 then over time, you see less of them. And we have 23 had only the expected amount of complications that 24 you get with any surgical procedure and had really 492 1 good outcomes with really satisfied patients by and 2 large. 3 Q In terms of successfully treating pelvic organ 4 prolapse over the time that you've seen your	Boston Scientific has previously designated this testimony and Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

5 patients over the last four or five years, have you 6 been pleased with the outcomes in terms of treating 7 their prolapse? 8 A I have been. I have been happy with the results that 9 I've seen going out even to five years after surgery.		
dm052314, (Pages 493:13 to 497:16) 493 13 Q Okay. In terms of -- Pinnacle went on the market in 14 January of 2008. 15 When did you start performing Pinnacle 16 surgeries in terms of when Pinnacle went on the 17 market? 18 A I performed the first Pinnacle procedure. 19 Q And so was that pretty soon after January of 2008? 20 A It was during January of 2008. 21 Q And you were asked some questions earlier about 22 clinical trials. 23 Were there any clinical trials 24 specifically with Pinnacle prior to going to market 494 1 in January of 2008? 2 A No, there were not. 3 Q Why were you comfortable using Pinnacle in January of 4 2008 in patients when there weren't clinical trials 5 specifically with the device? 6 A Because it's one of the important concepts that is 7 sometimes lost in this debate, and that is what I 8 have invented is an incremental improvement in the 9 way we tack mesh down. It's a new hammer; it's a new 10 screwdriver. 11 Mesh and grafts in general have been 12 used for many, many years to treat prolapse, and	Boston Scientific has previously designated this testimony and Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

there have been incremental changes throughout all of that time period. There's been vast amounts of research. In fact, there's far more research for the vaginal approaches to mesh than the abdominal approaches to mesh and, frankly, to the native tissue repair approaches to mesh -- to prolapse repair.

And so we -- in my mind and what I decided for my patients was that this was an incremental change in my tools. And surgeons change their tools all the time.

The procedure is mesh-reinforced prolapse repair, and the tools you use will evolve

over time.

Q Had -- mesh-enforced prolapse repair, had that been done prior to Pinnacle coming on the market?

A Yes. Mesh-reinforced prolapse repair has been a part of the armamentarium of urogynecologists for many years.

Q And has that also been true of polypropylene mesh-based prolapse repairs?

A Yes. Polypropylene has been, over the decade and beyond -- the last decade and beyond, the most commonly used graft.

Q You mentioned to the jury earlier that you use different techniques in treating pelvic organ prolapse; some native tissue, some abdominal sacrocolpopexy, and then some transvaginal mesh. Is that right?

A Yes. Q What is the benefit of having those different options in terms of treating your patients? A It's critical. It's critical because not every patient has the same need. And every surgeon, just like every orthopedist and every back surgeon, every heart surgeon, we have to make determinations about what's 496 best for this patient, is -- based on who that patient is and what her anatomy is like, as well, and what her wishes are. Because that's another piece that's forgotten in all of this, is that these patients -- that's one of the reasons that led me to eventually write a paper on informed consent, is a lot of this is -- you know, patients come in, and they'll tell you what their goals are. And a lot of patients, their goal is "Look, my friend, my sister, my mother has had three failures of the surgery, so one thing I'm looking for is a durable procedure. What can you do to give me a durable procedure?" Or in my practice, many of the patients have already had failures of their prior surgeries, and they're coming to me with that in mind. Now, that's not true for everybody. Some patients come with entirely different requests. And so it's really this joint		

22 decision, and you can only have that joint decision 23 if you have multiple ways to fix prolapse. 24 So every patient sees essentially that 497 1 slide that you had on the three different approaches, 2 and every patient I go through what are inevitably 3 the pros and the cons. 4 You can't ever set this up as if there 5 would be no cons to an approach because there's cons 6 to every surgery. It's why, in my own personal life, 7 I try to avoid surgery if I can. And whether that's 8 having a plate put in or a screw put in or having a 9 native tissue hernia repair, whatever your surgery 10 is, there are potential complications and there are 11 potential failures and you balance that out. 12 And every surgeon and every patient 13 makes that decision individually in this joint 14 process. Informed consent is a process. It's not a 15 document. It's not a piece of paper to be signed. 16 It's this process that you go through.		
dm052314, (Pages 498:23 to 499:18) 498 23 Q You were asked some questions about polypropylene, 24 the material that's used both in the Pinnacle device 499 1 in midurethral slings and in the Uphold device. 2 When Pinnacle came to market and 3 today, are you comfortable with polypropylene as the 4 material that's used to make those meshes?	Boston Scientific has previously designated this testimony and Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

5 A I'm comfortable with it based on the fact that there **6 has been volumes of literature and a large world** **7 literature review of all the studies that have** **8 been published.** **9 And I've had long experience with it,** **10 and I -- you know, back in the beginning, I** **11 trusted Dr. Julian's long experience with it that** **12 came before my long experience with it.** **13 And as I saw my patients back, I** **14 became increasingly more comfortable with it. And as** **15 other surgeons were adopting it and continuing to** **16 perform mesh-reinforced prolapse repairs and they** **17 found that utilizing this fixation device helped them** **18 accomplish it, that increased my confidence in it.**		

1. **Objections to Counter Exhibits.**

   a. BSC has previously designated Miller 1037 and 1038. Plaintiffs adopt and incorporate their objections as set forth in their counter designations, if any.

2. **Counter Exhibits to Counter Exhibits**

   a. Plaintiffs adopt and incorporate the exhibits designated in the counter designations for this witness.

DATED: July 20, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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